The American people will be looking at this House of Representatives wanting an assurance that we will return this country and its businesses to fair play and playing by the rules.

Mr. LAFALCE. Mr. Speaker, I thank the gentleman.

We have lost 5 to $7 trillion. Now a significant portion of that, not all of that, is because of corporate mismanagement, earnings manipulation by officers, by directors, by the auditors, by the research analysts having conflicts of interest, by inadequate regulation from the self-regulatory organizations, by inadequate regulation from the SEC.

We need to correct the problem. We need strong legislation to correct the problem. We do not need a powder puff effort. We do not need a cosmetic approach. And I urge everyone in this House to get behind strong meaningful legislation such as the bill that I have introduced that has been endorsed by so many consumer groups across America.

OVERPRICED PRESCRIPTION DRUGS

The SPEAKER pro tempore (Mr. KIRK). Under the Speaker's announced policy of January 3, 2001, the gentleman from Minnesota (Mr. GUTKNECHT) is recognized for 60 minutes as the designee of the majority leader.

Mr. GUTKNECHT. Mr. Speaker, let me say first before I begin on the issue that I really want to talk about tonight, I listened to much of my colleagues' Special Order for the last hour. And I have to say on behalf of most Republicans, and I think most Americans, we agree with what they have said.

The truth of the matter is when there have been frauds, and we have seen fraud committed against shareholders and against corporations, those people need to go to jail. And I think we are all in agreement on that. Frankly, I think just for the theater of it I would like to see some of these corporate executives that have been charged with crimes and will be charged with crimes, I would like to see them arrested and taken away in chains. I would like to see handcuffs on them. I think I speak for the overwhelming majority of people in this Congress.

I will say this: the one thing we have to be careful of is that we do not try to turn this into a partisan thing. I do not think this is a partisan issue. I think all of us can stand and talk about our moral outrage for some of the things that have gone on in corporate America, and the time has clearly come to clean them up.

I rise, though, tonight to talk about another crisis that all of us know about; and, frankly, we in Congress have done too little to really resolve, and that is the whole issue of about how much Americans pay for prescription drugs. It is a crisis particularly for those seniors, but not just seniors but for all Americans who do not currently have some kind of drug coverage in terms of insurance. And as we speak tonight, there are literally hundreds, if not thousands, perhaps even millions, of Americans who are having to make very, very difficult decisions about whether or not they can afford the drugs that the doctors say they need to regain their health. And I brought with me, and these charts are becoming all together too familiar to many of my colleagues, but I think they need to be restated because we have learned the more you learn about this issue, the more we can come together with some kind of a solution.

But I want to point out this chart because as I was going through my closet here about half an hour ago, I found this chart from last year. This is dated 2001. And I wanted to bring this with me to show you a couple of examples, and what we have here is a chart that demonstrates the price that Americans pay, the average U.S. price versus the average European price.

The source of this, these are not my numbers. This is from the Life Extension Network. It is an independent foundation that has been studying this issue for more than 10 years. They continue to come to the same conclusion and that is that for prescription name-brand drugs Americans pay more than anybody else in the world for the same drugs. There are a lot of reasons for that, and we will talk about that during this Special Order. But what is interesting to me is to see how prices have changed just since last year.

Now, this chart is about a year and a half old. And what you see, for example, let us take a couple of these drugs, Claritin, a very commonly prescribed drug, a lot of people are taking it now for allergies. It is about to go off of patent so you will see the price come down dramatically in the United States in all probability, although I will tell you the pharmaceutical company that makes it is trying to replace that with a drug called Clarinex. Now according to at least one report, Clarinex is a better drug than Claritin. It is 2 percent better. That is not a huge improvement for the difference in price. But the thing that bothers me is that the average price for Claritin in the United States was about $63.06 for a 30-day supply. That same drug sold on average in Europe for $16.05.

Another commonly prescribed drug is one we have talked about here on the House floor because my 84-year-old father takes this drug every day. In fact, many senior take it. It is called Cumadin. It is a blood thinner. It is a very good drug. It is more effective than asprin, and if you have had a stroke or if you have had a heart attack, if you have got a problem with blood clotting and platelets and so forth, it is a very effective drug.

Let me say from the outset, I am not here tonight to beat up on the pharmaceutical industry. I am not here to say shame on the pharmaceutical industry. They are only doing what any free enterprise company would do in terms of exploiting a market opportunity that we have given them. No, I am not here to say shame on them. I am here to say shame on us because we have created this situation and we need to change it.

Let us talk about Cumadin. Last year the average price, a year and a half ago in the United States was about $37.74. The average price in Europe was $8.22. Now, that price has changed.

I will pull up the next chart, which is this year's prices; but as we go down the list, we have seen the big differences. When you get into some of the very expensive drugs, Zithromax 500, United States price for a 30-day supply, $486. The same drug in Europe made in the same plant under the same FDA approval sells for $176. Huge differences.

There are some where the differences are less. You look at, for example, Lipitor. The average price for Lipitor in the United States, $52.86. In Europe, $41.25. Again, these prices are about a year and a half old.

Let me show some of the current prices because some of these drugs have changed dramatically in just a year and a half. I mentioned last year that Cumadin in the United States the average price was $37.74. In just a year and a half that price has gone to $64.88. Now, that makes me angry to see that huge difference because nothing has changed. It is exactly the same drug, put in exactly the same capsules, under the same FDA approval and the same FDA plants.

The interesting thing, too, is as far as I know there have been no major lawsuits so they have not had this tidal wave of litigation that we sometimes hear about. So the price has almost doubled in just about a year and a half.

Now, it makes me feel just a little better that the price in Europe has doubled as well. The price has gone up uniformly, but the price is Europe today is a little over $15. The price in the United States is $64.

□ 1845

One that has really gone up as well is glucophage. Glucophage is a marvelous drug. If a person suffers from diabetes, glucophage has changed their lifestyle. It is a fabulous drug, and the manufacturers deserve credit for what they have done for all of the millions of people, not only here in the United States, but around the world, who suffer from diabetes.

The price has gone up now to an average of $124.65 for a 30-day supply in the United States. The average price in Europe, $22, $22. Some people will say, well, how can that be, how can it be that the prices are so much different? Let me just, first of all, say that many other countries do have various forms of price controls. We have price controls on hospitals and doctors and medical providers under Medicare as well. We determine how much they can charge, and essentially with some of

the countries that is what they have done. They have price controls on these drugs, but that is not universally true.

If we look at countries like Germany and Switzerland, where a number of the big pharmaceutical companies are based, Germany and Switzerland, as far as I can tell, do not have what we would describe as price controls. Let me give my colleagues a couple of examples, and these again, these are charts, the numbers are provided by the Life Extension Foundation. If any of my colleagues would like to take a look at these charts, they can just go to my Web site at gil.house.gov and we have this chart up there and have more information about the differences between what Americans pay for prescription drugs and what the rest of the world pays.

I was not completely satisfied just to use the numbers that we had received from the Life Extension Foundation, so we had one of our friends, or some friends in Europe, buy some drugs for us, so according to the FDA what I am holding up right now are illegal drugs. The FDA holds that it is illegal to bring these otherwise FDA-approved drugs, made in FDA-approved facilities into the United States. They do not always enforce their rules. For personal use, if a person brings them back with them from Europe or Canada or other industrialized countries, generally speaking, the FDA will not enforce what they believe are their own rules.

Let me show my colleagues this drug. It is a drug called Zocor, and this drug was bought about 3 weeks ago in Europe. In fact, I think I can even tell my colleagues where it was purchased. In fact, the story of Zocor is even more interesting because it is manufactured by a subsidiary of the Merck pharmaceutical companies. It was manufactured and distributed in Italy, and this was bought in a pharmacy in Como, Italy. The price for this Zocor in Como, Italy, was 13.94 Euros. The day that this was purchased, the American conversion on that was $14.77.

I am sorry, it was 14.77 Euros; the American price is $13.94.

I have a good friend who runs a pharmacy in Northfield, Minnesota, and so we called him and asked how much this exact same package of Zocor would sell for here in the United States in Northfield, Minnesota. The price, as I say again, in Europe was $13.94. This drug bought at the pharmacy in Northfield, Minnesota, is $45. I am not good in math, but that is more than five times the price, I am sorry more than four times the price for the same exact drug.

We also checked on another drug, Claritin. Interesting story about this particular drug. This drug is manufactured by, actually, a Swiss company by the name of Schering Plough. Many of us know the name of Schering Plough, but many do not know that it is a Swiss company. But the interesting thing is, this drug was actually manufactured in Spain and it was reimported into Germany where, as I say, they do not have price controls, but they do have open markets, and the Germans have the right to shop where they can get the best price.

This Claritin, manufactured by Schering Plough, a Swiss company, manufactured in Spain, was bought in Germany at a pharmacy in, let me get the name, in Riegensburg, Germany. It was purchased for 14.8 Euros; the American conversion that day was $13.97. Again, we called my favorite pharmacist in Northfield, Minnesota, and asked him how much this package of Claritin would sell for in Northfield, Minnesota, and the answer is $64.97; $13.97 in Germany where they have no price controls, $64.97 for the same drugs.

We have to ask ourselves, why do we permit this to happen? We have open markets for almost everything else. How can it be that we are paying so much?

Let me come back to something else. Let me talk about open markets and what open markets do for us every day. Some people say, well, if we open markets and if we allow Americans to purchase these drugs in other countries, there is a risk they may get the wrong drug or they may get a drug that has been adulterated or they may get a drug that is counterfeit. Well, that is true.

I must tell my colleagues that is true, but every year we, as Americans, consume enormous amounts of food that comes in from other places. For example, last year in the United States of America, we imported 500,000 tons of pork. I love pork. In fact, we produce a lot of pork in my part of the district. In fact, we produce one of the world's finest luncheon meats. It comes in a blue can with yellow lettering. It is called Spam. Every day in Austin, Minnesota, we turn 16,000 pigs into Spam.

I love pork. It is a wonderful product, and if it is managed properly, as far as we know, no one has ever gotten sick of any food-borne disease from eating Spam. It is a wonderful product. But the truth is, by eating imported pork, which is almost never inspected, and again, I want to give my colleagues that number, 500,000 tons of pork is imported. If a person eats pork that has not been properly refrigerated and so forth, they can get salmonella from pork, they can get trichinosis; and either one of those diseases can kill a person.

So some people say, well, if we import these drugs people might die. We keep records. In the last 10 years, according to the Food and Drug Administration, and the FDA that is responsible, that literally has built this wall, that says Americans cannot import or reimport legal, FDA-approved drugs into the United States, they are the ones who have literally made it possible for the drug companies to have one pricing strategy for Americans and another pricing strategy for people around the rest of the world. Our own Food and Drug Administration admits in their own studies that of the hundreds of thousands of tons of fruit and produce that come into the United States every year, at least 2 percent of them are contaminated with food-borne pathogens, including salmonella. Salmonella can kill a person. It is a very dangerous food-borne pathogen.

At the same time, they keep records, though, of how many Americans have become ill or died from taking legal, FDA-approved drugs that came in from other countries. Do my colleagues know what the answer is? Zero. No one, no one has gotten sick or died from taking legal, imported drugs from other countries.

I have had town hall meetings around my district, and I can tell story after story, but I would like to share at least one of them with my colleagues.

It is about a lady who was traveling in Europe and was traveling in Ireland, and she has a special skin condition. I think it is called eczema. She has to take a special cream, and it works very well, and again we thank the pharmaceutical companies for coming out with these marvelous drugs that help us all live better, but she ran out of that cream while she was traveling in Ireland, and she stopped in to just a local pharmacy.

She was a cash customer. She walked in and she happened to have her prescription with her. She walked up to the pharmacist and said, could I get this prescription refilled here at this pharmacy, and he looked at it and he said, well, absolutely, and he sold her the cream. The price was $30 American. The price she says in the United States, and she uses about one tube every month, is $130. The difference in Ireland, $30; in the United States, $130.

She got back to the United States, and as is always the case, on the outside of the little box of the prescription ointment was the name, the address and the telephone number of that pharmacy back in Ireland, and so as she began to get low on that tube of ointment, she did what a lot of us would do. She picked up the phone and she called that pharmacy in Ireland and asked if she could have the prescription refilled, and he said, sure, and I think she gave him her credit card number.

He put it in a package and shipped it. I do not know whether it was FedEx'd or UPS'd or Parcel Post. I am not sure but when the package came through Customs, our own Food and Drug Administration intercepted that package, and they just opened it and they put a threatening letter in that package and ultimately sent it on its way to the lady and said this may be an illegal drug here in the United States, and in a sense they said if you try to do this again, you could be prosecuted.

If a person is a retired single woman and they get a threatening letter from their own Federal Government, that is a pretty intimidating thing and that is what the FDA has been doing. They have been concentrating on honest, law-abiding citizens who are trying to

save a few bucks because, for her, if she could buy that drug in Ireland, it would save her $1,200 a year, and for her, $1,200 is a lot of money. Let us be honest, for all of us, $1,200 is a lot of money.

My vision, I want to make this clear, too. I want to include pharmacists in this whole thing. I want to be able, so that my dad or my wife or anybody who may be watching this particular C-SPAN program would be able to go to their local pharmacy and they would talk to their local pharmacist and say, listen, I need to renew my prescription for, pick one of these drugs, just name it, Claritin, I need a 3-month supply.

The pharmacist ought to be able to say to them, listen, I can fill it out of my inventory of United States supply, and they force me to charge $89, or I can go on line and I can order it for you out of the pharmaceutical supply house in Geneva, Switzerland. We will have it shipped to you FedEx in about 3 days, and your price will not be $89 or $64, your price will be $16, plus about $8 shipping and handling.

Which one would my colleagues prefer?

If we multiply that by a 3-month supply, we are talking about 3 months. We want to keep the pharmacists involved because pharmacists play a very important role in the health care delivery system here in the United States, and we must not forget that.

I want to show my colleagues some other charts here because I think they deal with some of the arguments that we hear around this building which, in my opinion, are pretty much nonsensical, and I have already talked a little bit about. Some say that importation jeopardizes consumer safety, but as I said, the truth is, there is no known scientific study that demonstrates a threat of injury to patients importing medications with a prescription from industrialized countries. Zero, zero.

As I say, more people have gotten sick from eating imported strawberries. Thousands of people have gotten sick from eating imported strawberries, and we bring thousands of tons of strawberries into the United States every year and people get sick, and the Food and Drug Administration does almost nothing to stop it.

What is more, millions of Americans have no prescription drug coverage. Stopping importation of FDA-approved drugs threatens their safety. A drug that a person cannot afford is neither safe nor effective, and millions of Americans today, because they cannot afford the drugs, are going without the drugs, and so that drug is neither safe nor effective.

Let me go to the next question people raise. Some say that the FDA lacks the resources to inspect mail orders. The truth is the FDA is focusing on the wrong problem. They are putting all their resources, instead of stopping illegal drugs imported by illicit traffickers, they are spending all their time enforcing their so-called rules on approved drugs imported by law-abiding citizens. We are again talking about FDA-approved drugs from FDA-approved facilities, and let me just say this for the benefit of Members.

There are only about 600 FDA-approved drug-making facilities in the world, and they inspect them regularly. We know what they are doing. They want to have FDA-approved facilities so that they can sell not only in the United States, but around the world.

So far, last year, the FDA detained 18 times more packages coming in from Canada than Mexico. Why are we putting so much emphasis on trying to stop imports from Canada rather than Mexico? I am not saying anything disparaging about Mexico, but if we have a problem with drugs, counterfeit drugs, drugs that have been adulterated in some way, it strikes me that we have a bigger problem with Mexico than we do with Canada, and yet we have stopped 18 times more packages from Canada than we have from Mexico.

Worse, last year, this was a year and a half ago, Congress appropriated $23 million for border enforcement, but the Secretary of Health and Human Services at that time ultimately decided not to enforce that particular provision and refused to spend the funds.

Let me go to this next chart. Some say that a Medicare drug benefit will eliminate the need for importation, and we passed a pretty important bill in the House last week. I voted against it for a variety of reasons, but the truth is simply, shifting high drug prices on the government only transfers the burden to American taxpayers. It does not solve the problem.

□ 1900

Americans are paying far too much. Moreover, Medicare coverage will not help the millions of Americans that do not have prescription drug coverage in their health insurance plan.

Let me finally just show this last chart. Some say that importation is merely an indirect way of enacting price controls. But the truth is importing prescription drugs into the United States will lower prices here and, in the long run, force Europe to pay more of the drug research and development cost. The best way to break down price controls is to open up markets.

I did not say that. That is not a quote from me. That came from Steve Schondelmeyer, who has a Ph.D. and is a pharmacology professor and director of the Prime Institute at the University of Minnesota. He is the one who said the best way to bring down or to end price controls is to open markets.

And for those who do not believe it, look back at what happened to the former Soviet Union. When President Reagan went to Berlin and said, Mr. Gorbachev, if you mean what you say, come here to Berlin and tear down this wall. And he knew better than anybody that markets, and as he said, markets are more powerful than armies. What ultimately brought down that wall more than anything else was they could not hold back free markets. And, my colleagues, neither can we.

Finally, let me just say that when we talk about how much Americans pay for research, and the drug companies are all saying, well, if we bring down the prices in the United States, and incidentally we believe that if we just open up markets we will see prices of prescription drugs in the United States come down by at least 35 percent, but some people say, well, if that happens, we are not going to have any money to spend on research. My colleagues, people need to know how much we subsidize research in the United States.

We often hear that the United States, the American people, represent roughly 4 percent of the world's population, and we consume 20 percent of the world's energy, and we consume 30 percent of the world's paper, and 30 percent of this and 22 percent of that. But, my colleagues, most people do not know this. We may represent 4 percent of the world's population, but we represent 44 percent of all the dollars spent on basic research. Americans are paying more than their fair share for the cost of research.

We subsidize that research in three separate ways here in the United States, and we all need to be aware of this: first of all, we subsidize it through government-paid research. This year, we will spend roughly $21 billion in basic research through the NIH, the National Science Foundation, and others. Twenty-one billion for basic research will come out of this Congress and go into research, which ultimately the pharmaceutical companies know much of that research they can use to their benefit at no cost. The results of that research is published on the Internet and is available to everybody essentially free of charge.

The second way we subsidize them is through our Tax Code. Now, if they are profitable companies, and these are the most profitable companies in the Fortune 500, they are at a 50 percent tax bracket. So 50 percent of the research right off the top is written off on their Federal tax forms. Now, on top of that, many times they get tax credits. Some of them have moved their operations to Puerto Rico, where they pay no taxes; and as a result, we are subsidizing them through the Tax Code in several ways.

Finally, we subsidize in the prices we pay. When we are paying two, three, four, five times as much as they pay in Europe for exactly the same drugs, we are paying more than our fair share for all of the cost of research. We ought to pay more. And let me just say that, and I have said this on the House floor, and I will say it again and again. I am more than willing as an American consumer, and as a public policymaker and

a Member of Congress I think Americans ought to pay our fair share. I appreciate what the pharmaceutical industry has done. I appreciate the miracle drugs they have come out with. I am willing to pay more than the starving people of central Africa, but I am unwilling to continue to subsidize the starving Swiss.

The time has come for Europe, for Canada, for Japan, and the other industrialized countries around the world to pay their fair share. And the easiest, simplest, fastest, least bureaucratic way to do that is to open up the markets. I will repeat again to congressional leaders: If you mean what you say about free trade, whether we are talking about blackberries, whether we are talking about blueberries, whether we are talking about bananas, whether we are talking about pork bellies, or whether we are talking about Biaxin, then come here to the floor of this House, come here and tear down that wall, because that is the way we are going to bring down prices.

When we do that, it will be much easier for us to provide the kind of coverage that Americans need, particularly seniors in Medicare, if we can come up with a plan that will reduce those prices.

Mr. Speaker, with that, I yield to my close friend and dear colleague, the gentleman from the great State of Georgia (Mr. KINGSTON), who has been a fighter in this battle for a number of years with me.

Mr. KINGSTON. Mr. Speaker, I thank the gentleman from Minnesota, and I wanted to say that I did not catch all of the gentleman's remarks on the way over here, so some of this may certainly be repetitive; but first of all, I think we need to say a word of thanks to the chairman of the Committee on Energy and Commerce, the gentleman from Louisiana (Mr. TAUZIN), and also to the House Republican leadership for scheduling some hearings on the drug reimportation issue. I am very excited about the hearings.

Because when people around America see some of the differences in the costs, and I see the gentleman has his latest chart up there, for instance with Premarin, and if I am reading it correctly, it is $55.42 in America compared to $8.95 in Europe. A statistic that our friend and colleague, the gentleman from Vermont (Mr. SANDERS) has brought up is that the Boston University School of Public Health, a particular professor there, says that America could save $38 billion a year if American consumers could buy medications at Canadian prices. Of course, the gentleman has European prices on there, but we have also other charts with Canadian prices, and they are just as attractive as the European prices.

What is odd, and I just want to enter into a dialogue with the gentleman, does the gentleman know how many people it is that have died because of drug reimportation? Surely it must be thousands upon thousands, given the great resistance some Members of Congress have to this.

Mr. GUTKNECHT. I mentioned this earlier. The Food and Drug Administration does keep pretty good records, and we know that thousands of people have become ill and died as a result of eating imported foods that were contaminated with some kinds of foodborne pathogens. As best we know, with the latest numbers we have over the last 10 years, the number of people who have died as a result of taking a legal drug imported from an industrialized country, that number is zero.

Mr. KINGSTON. Zero people.

Mr. GUTKNECHT. Zero. Not one. And let me say that we pay a very dear price for what apparently is no real protection.

Mr. KINGSTON. So for $38 billion more in expenses a year, it appears that there was no real difference in public health.

Mr. GUTKNECHT. We do have to ask, Who are they protecting us from?

Mr. KINGSTON. Now, there is a statistic, though, that the Secretary of Health and Human Services gave to the gentleman and myself recently that 98,000 people a year actually do die from misapplication of prescription drugs, not taking their medicine properly or timely. And I know that the University of Minnesota, which I think is not in the gentleman's district, has done a study to find something like 40 percent of prescription drugs are used incorrectly. Is that the gentleman's understanding?

Mr. GUTKNECHT. I believe that is correct. That was a study that was done at the University of Minnesota, and I believe the gentleman's numbers are correct; that literally tens of thousands of Americans become seriously ill or die every year from not taking their medications correctly.

And we do not know at this point, based on that study, how many of them were cutting their pills in half or were mixing medications that they should not have mixed. Which brings me back to the point I did make before the gentleman came over, and that is our vision is to keep the pharmacists involved. We believe that the pharmacist is a very important component in the health care delivery system. They are the ones who know how drugs interact and how these drugs should be taken; whether they should be taken at mealtime or before bed, whether they should take a whole glass of water or drink with milk.

There are a number of different things that are important; and we know an awful lot of people do become ill, thousands, tens of thousands, because they take the drugs incorrectly or they mix and match drugs they should not.

Mr. KINGSTON. I believe the last vote we had on this was July 10, 2000, which was, well, 2 years ago today, but at that point out of 435 Members, 363 voted in favor of drug reimportation. And, again, that was July 10, 2000.

To make sure folks understand, we are talking about drugs that have strict FDA oversight, proof of FDA approval of imported medicine. There must be a paper chain of custody so people know that they are not counterfeit drugs. We are also stating that only licensed pharmacists and wholesalers can import medicines for resale, not just somebody who decides to open up a shop somewhere. Importers would have to meet requirements for handling as strict as those already in place for existing manufacturers, and a registration of Canadian pharmacies and wholesalers who would be selling or exporting to America would need to be registered with Health and Human Services. And we would need to have lab testing to screen out counterfeits.

And counterfeit drugs can happen under the current market. This does not change the threat of counterfeit drugs.

Mr. GUTKNECHT. If the gentleman would yield, we know of at least one example that was well publicized of a pharmacist in the Kansas City area who was adulterating drugs. He was a licensed pharmacist, and he was ultimately caught. We do not know how many Americans ultimately died or lives were shortened or lost their health as a result of what he was doing. But that did not happen because of drugs that were being imported from a pharmaceutical supply house in Geneva, Switzerland. That happened right here in the United States of America, in Kansas City, Missouri.

Mr. KINGSTON. Well, I think that is important to point out, because people often bring up this counterfeit drug situation, and it is something that certainly scares us. My mother had breast cancer this year and has to take Tamoxifen, and I certainly want to know that the pill she is taking is as represented. I do not want any counterfeit pill for any American.

But it is a red herring to mix that with the reimportation question, because counterfeiting is taking place today without reimportation.

But another issue that I wanted to mention to the gentleman is one about the patent bill that our colleagues, the gentlewoman from Missouri (Mrs. EMERSON) and the gentleman from Ohio (Mr. BROWN), have been pushing. Now, as I understand it, and I do not know if the gentleman has covered this already, but most drugs have a 17-year patent. When that patent expires, in order for a generic company to get to make that name-brand drug, they have to file, I guess with the FDA.

If the gentleman has a definition for generic drug, maybe he could share that with us.

Mr. GUTKNECHT. Let me share with my colleagues and those who may be watching, because this is something I did not know until a few years ago.

Before somebody can begin to make a generic drug, the patented drug, the name-brand drug, that patent will have had to expire. Or sometimes they will

turn them back. Occasionally, they will turn them into an over-the-counter drug before the patent expires. But the point is, they have to go to the FDA and ask for approval just as if it were a new drug they were making, a brand-new drug.

What they are doing is they are copying the recipe for that drug, and they have to prove to the FDA beyond a shadow of a doubt that the difference between their drug, the generic drug, and the name-brand drug will be no more than the difference between one batch of the name-brand drug and the next batch.

Sometimes there is an impression left with people that, oh, if you take the generic drug, that is inferior to the name-brand drug. It simply is not true. The active components are identical in every way to the name-brand drug. And the savings can be 60, 70, 80, or 200 percent.

Mr. KINGSTON. So if I follow the gentleman, it is not going to be a substitute, for instance, Coca Cola with Pepsi Cola, two products that are very similar and neither one would cause any problems. The gentleman is not saying that at all. What the gentleman is saying is that we are simply taking the Coca Cola that is in this nice traditional Coca Cola can and pouring it into a cup, but it is the same content inside. The same brand-name inside that pill, is what a generic drug is, then.

Mr. GUTKNECHT. I will give an even better example. Go down to the Mint here in the United States capital, just a few blocks down here. They print $1 bills. What I am saying is the difference between one sheet of $1 bills will be no different than the next sheet.

Mr. KINGSTON. So that is it. I think it is very important because there is this stigma promoted by the name-brand drug companies, and I certainly can understand why they want to do it, but there is a stigma about generic drugs.

But getting back to the patent issue, when the patent expires on a drug, the generic company files with the FDA to say that they want to start making that drug. The FDA can say yes or no.

□ 1915

And if the name brand company protects it and says we are changing this drug, then they get a 30-month extension; is that correct?

Mr. GUTKNECHT. Mr. Speaker, that is my understanding, that almost any minute change, including changing the color of the tablet, if they say we are going to change the color of the tablet because it will increase the effectiveness of the drug or its shelf life, they almost automatically get a 30-month extension. And a 30-month extension is worth an enormous amount. But from the other side, that is an additional expenditure that American consumers have to make.

Mr. KINGSTON. And seniors who have to choose between drugs and food, in many cases they are going without medicine.

Prozac went off patent last August; is that correct?

Mr. GUTKNECHT. I am not sure if it has, or is in the process of going off patent.

Mr. KING. How much has the price fallen?

Mr. GUTKNECHT. Mr. Speaker, according to these charts, we have not seen a dramatic reduction.

But Claritin and Clarinex are a good example. Claritin is going off patent and so the drug company that manufactures it is in the process of converting people from Claritin to Clarinex. According to one published report, the improvement, if you can say the quality or the effects of moving from Claritin to Clarinex, and Claritin will soon be available in generic if they do not get a 30-month extension, which I do not think that they should, but the difference is 2 percent. One of the published reports says there is a 2 percent advantage in taking the Clarinex over Claritin.

What the drug companies try to do as they have a drug coming off patent, they try to come out with a new and improved version, which I appreciate, but a 2 percent improvement hardly justifies a $60 a month difference in price.

Mr. KING. Mr. Speaker, the patent issue is a separate issue from reimportation, but we are all interested in making drugs affordable and accessible to the seniors of America. The Republican Party has made that one of its top issues this year.

To just review the patent situation, if you invent a computer chip like Steve Jobs, the proverbial dot.com success story, if you do that tinkering away in the midnight hours at your house, you get a patent. That patent helps you recoup the costs and all your time and pays you off for your ingenuity and genius mind.

With a drug company, they are a little different. The research is subsidized by the taxpayers, so why are we giving them such a long, 17-year patent when in fact so much of the research is subsidized?

Mr. GUTKNECHT. Mr. Speaker, I think that is a fair question and I am not sure I can completely answer the question. That has happened with the taxpayers have underwritten most of the cost of developing at least the basic formula for a new drug, and then the company has gone out and patented that, and they have reaped all of the benefits. In fairness, they probably pay over the life of that drug, they pay an awful lot of taxes and so we recoup some of that through taxes. But the question is a fair one.

If a drug is developed mostly with taxpayer-funded research money through the NIH or other Federal grants, the taxpayers should get some kind of royalty and that is a question that we have not resolved. Frankly, we may need some help from the Secretary of Health and Human Services, the people at NIH, the National Science Foundation, as well as some of the folks at the Patent Office.

I am delighted to hear that we may have a hearing on this whole issue in the Committee on Energy and Commerce, and I hope we can bring some of those people in to explain to us as policymakers and to the people of the United States how it is that we can get shorted on both ends. In other words, we pay for the research and we pay exorbitantly high prices for the drugs relative to the rest of the world.

Mr. KINGSTON. I think the patent issue is one that we should discuss. On Glucophage, which is for diabetes, has the 17 years on that patent run out?

Mr. GUTKNECHT. I do not know about that one. I know some of the most important drugs for diabetes have literally been off patent for several years, or had their patents renewed. A number of these drugs were developed 50 years ago and are still being sold at relatively high prices, and the company has recovered all of what you could remotely suggest is a cost, and still have received additional patent protection from the U.S. Patent Office.

Mr. KINGSTON. So a patent, if it is gamed properly, it can be a government-sanctioned monopoly for drug companies.

Mr. GUTKNECHT. I think it was Glucophage that originally you had to take twice a day. There is a legitimate question whether or not they should have gotten an extra 17 years simply because they went from a two-a-day capsule to a once-a-day capsule.

Mr. KINGSTON. I think we should look at that with a very large magnifying glass because with what we are seeing with corporate greed, and there are a lot of great corporate citizens and CEOs, but the accounting games which seem to have been pulled by the Global Crossings of the world, and the Enrons and the Arthur Andersens, it seems like big corporations are just in it for themselves and are not worrying about the good of humanity.

One of the things that we in the Republican Party did April 24, we passed an accounting accountability act to separate accountants from consultants and put things at arm's length. I am glad to hear that the Senate is waking up to this. I am glad to hear that Mr. DASCHLE and the other body has discovered there is an issue out there. We did ours on April 24. The Democratic leadership voted against it. It is time for the Senate to act on it. Let us get a bill into conference and hammer out the differences.

I think right now it is time for corporate goodwill to be exhibited. It is not time to game the accounting procedures and patent procedures. Maybe we as a Congress should look at an issue of patents and when are they legitimate and when are they not legitimate.

I know one thing that we have also done, switching back to the prescription drug issue, is shortened the drug

approval time for FDA. FDA under the Clinton administration was taking about 8 years to approve a new drug. Today that is down to 2 to 3 years, and a lot of that progress was actually made under the Clinton administration as well, so I want to give them a compliment where compliments are due.

Mr. Speaker, 3 years is probably as short a time as we are going to get. I believe 2 years and 1 month on an average, and generics sometimes can take a little longer. But one of the things that our constituents complain about is a drug for cancer or epilepsy that is being used in France or another country, it has a track record and has been on the market for 15 or 20 years but it is not approved in America. I think for that reason we have to keep the heat on the FDA to get drugs approved faster.

Mr. GUTKNECHT. Mr. Speaker, I think the whole issue of reimportation will begin to force that issue. The question we are really asking today is how safe is safe. What is the FDA protecting us from? In their effort to make us absolutely safe from any imported drug that is clearly legal in the United States, and to keep us safe from drugs that have already been approved in other parts of the world, they are putting roadblocks in the way, and in many cases are costing American lives and not improving their health.

I think the question we have to ask as policymakers is how safe is safe enough. As I mentioned earlier, we import 500,000 tons of pork every year. You can get sick and die from bad pork, and yet 500,000 tons is imported every year with very little inspection by the Food and Drug Administration.

I think we have to be honest with ourselves. Even with all of the time and research that goes on, some people are going to have an adverse reaction to some drugs. That is just absolutely going to happen. Some people are going to take a drug, and they are going to get well. Some other people may get sick, and some might die from taking that drug.

There were some studies that came out on Premarin and Prempro. They are female hormone drugs. They come from horses. We have known about them for literally years and years. What we did not know, that by taking these two drugs, either of these drugs, you may begin to develop and have a significantly higher rate of breast cancer, heart disease and other diseases. I do not know what the future is going to be, but the point is we studied these hormone replacement therapies for years, and yet we did not know what we now know today about those drugs.

I think we have to ask ourselves how safe is safe. Is the FDA really protecting us from serious injury, and we want them to do that, or are they being so careful, both on the reimportation side and on the approval side, that they are endangering American lives? We are asking them for a serious analysis, and compare what we do in the United States with what they do in Europe. Ultimately I think we will get drugs on the market faster, we will get generic drugs on the market faster, and if we have reimportation, we will get much cheaper drugs.

Mr. KINGSTON. In terms of tort reform, what the drug companies are also telling us is in the two examples the gentleman gave us, if a woman is taking a hormone-enhancing drug and because of research down the road, for whatever reason, that drug develops or accelerates the development of breast cancer, the drug company, of course, is going to get sued. What kind of protection should the drug company have, if any, in terms of tort reform or liability?

Remember, when you go to court and you sue, you can get compensatory damages for the money you have lost. Then there is noncompensatory damages, and that is for pain and suffering. And that is harder to calculate, but still possible, it is an agreed-upon figure.

A third kind of damage is a punitive damage where the State holds up the tortfeasor, in this case the drug company, as an example to others who would exhibit negligence, and punitive damages really was more for intentional or gross negligence, but lately it has not been.

It would appear to me that limiting punitive damages at some point is sensible because the victim is already going to get compensatory and noncompensatory damages. We have not had much success with tort reform. Is that going to be part of the solution?

Mr. GUTKNECHT. Mr. Speaker, I think it definitely needs to be part of the solution. I think part of the reason that health care costs are so high in the United States relative to the rest of the world is the fact that we have literally allowed this jackpot justice.

Now, I do not think that the manufacturers of any of these drugs have intentionally put those drugs on the market knowing that they were going to have these adverse consequences to whatever percentage of the people who take them. I think they have put these drugs on the market in good faith believing that the patients would receive a real health benefit from taking these drugs.

My view of tort liability is much more restrictive. I am not an attorney. I do not play one here in Congress. I do not think the gentleman is one, either. I think we have allowed this whole system to go out of control, and we all pay for it. They have a much more restrictive system in Europe, and that is part of the reason the drug companies are willing to sell the drugs for considerably less in Europe than in the United States. So long term, this needs to be part of the solution.

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Mr. KINGSTON. Mr. Speaker, may I say the gentleman has brought back his chart on the cost of drugs, and that is an astronomical figure, $1.8 trillion. In fact, there is a book that was written in Georgia several years ago that is called The Coming Economic Earthquake. You may have read it, a Georgia author, so I have to brag on him.

He is saying the difference between 1 million and 1 trillion is that if you took $1,000 bills, to stack them up to get to $1 million, stack one $1,000 bill on top of another $1,000 bill, it would be about 4 inches high. That would become $1 million at 4 inches. To get to $1 trillion, it would be 33 miles high. People do not understand that.

Mr. GUTKNECHT. One million $1,000 bills would be 4 inches high?

Mr. KINGSTON. $1 million, 4 inches.

Mr. GUTKNECHT. Of $1,000 bills.

And to get to $1 trillion, how high?

Mr. KINGSTON. Thirty-three miles.

Mr. GUTKNECHT. Thirty-three miles?

Mr. KINGSTON. Thirty-three miles. That is from Larry Burkett in The Coming Economic Earthquake.

Mr. GUTKNECHT. Again, these are not my numbers, I am not making these things up. The only thing we have done in terms of real raw research is we had these drugs brought in Europe, and we found out what they were in Northfield, Minnesota, for the same drugs. But the other charts came from the Life Extension Foundation.

This number comes from the Congressional Budget Office, and they are the official scorekeeper of what they think things are going to cost as we go in the future. Now, they could be wrong. They could be high, they could be low. But this is their best guess in terms of how much seniors will pay for prescription drugs over the next 10 years. That is $1.8, and then a zero - zero - zero - zero - zero - zero - zero - zero - zero. It is $1.8 trillion.

Mr. KINGSTON. Excuse me, but that is just seniors.

Mr. GUTKNECHT. That is just people over 65. That is just seniors. That does not include you and me and our kids and grandkids and whomever, all the other people.

Mr. KINGSTON. How many people are over 65 are on a fixed income? Is it not about 70 percent?

Mr. GUTKNECHT. Yes.

Mr. KINGSTON. That $1.8 trillion is going to be paid by 70 percent of the people on a fixed income. That is incredible.

Mr. GUTKNECHT. Here is what is interesting. Again, this is not my number, but this is what outside experts have told us, that if you just do reimportation, just reimportation, allowing seniors or anyone to go to their local pharmacy and at least price-shop from country to country to get the best price on the same drug, our estimate is you could save 35 percent.

Now, 35 percent of $1.8 trillion is $630 billion. That would go a long ways to helping to pay for the prescription drug coverage for those people who are currently falling through the cracks. We are talking about real money.

I think Everett Dirksen said a billion here and a billion there, and pretty soon you are talking about real money. $1.8 trillion times 35 percent, $630 million is a whole lot of money.

I want to congratulate our colleagues for the bill we passed last week. There are a lot of good things in it. But I do want to chastise them on this. The author of that bill stood here in front of this very microphone and said his plan would save about $18 billion over 10 years. Well, that is good. $18 billion versus $630 billion. I will ask America which program they want.

Mr. KINGSTON. Well, I think that it is sensible to explore both options.

Mr. GUTKNECHT. Right.

Mr. KINGSTON. I did support the Tauzin bill, the Thomas bill, the one the gentleman from Ohio (Mr. PORTMAN) and the gentlewoman from Connecticut (Mrs. JOHNSON) and so many others on the Committee on Ways and Means and Committee on Energy and Commerce, the gentleman from North Carolina (Mr. BURR), have championed.

The way I understand that bill, it is basically for a premium of about $35 a month, seniors on a voluntary basis would enroll in a program where they would take a $250 deductible, and from $250 to $1,000 Medicare would pick up 80 percent of the cost of drugs; then from $1,000 to $2,000, Medicare would pick up 50 percent; and then there is a gap, and there is a reason for that.

Most of the people are going to fall under $2,000, but from $2,000 to about $3,800, the senior would pay for 100 percent. Beyond that, Medicare picks up the tab. So you have catastrophic coverage. Unfortunately, there are a lot of people these days having to pay $6,000, $7,000, $8,000, $10,000, $20,000 a year on drugs. But so many people are in a lifestyle now where they have to take three, four, five, six pills a day.

I talked to a man over the weekend or over last week at one of my 11 town meetings, and he is actually having to take 2 pills a day, $17 each. So he is having to spend each and every day $34 on just two pills. He is only 51 years old. I hope he lives 50 more years at least, but the reality is, can you imagine at age 51 having to pay $34 each and every single day?

These miracle drugs are important. They have done a lot. They reduce our pain, they give us a better quality of life, they keep us out of the hospital, so there is no argument about you are going to take your medicine. But the cost of it is phenomenal.

I do think that the Republican Party took a very significant first step on a bipartisan basis the week before last with the prescription drug plan. I hope that the other body will act on theirs and maybe we can get together. But the point is, we have taken a very significant step. But I certainly agree with the gentleman that the next logical step is drug reimportation.

Mr. GUTKNECHT. We only have about 1 minute left. I want to thank the gentleman for joining us for this special order tonight. I certainly agree with the gentleman. I think it is time we do something in terms of covering those seniors falling through the cracks, but I think as I said, and the gentleman and I both said at a news conference a few days before the vote on that bill, that the real issue is affordability. If we are to do our job and effectively deal, we cannot sustain this kind of a chart. With 19 percent increases in the costs of prescription drugs and 3.5 percent increases in Social Security cost-of-living adjustments, that just cannot last.

We have to do more on the affordability side so that we can do more on the coverage side, and reimportation, reforming the FDA, reforming the tort liability laws, making it easier for generic drugs to come on the market, all of those things will go a long ways toward making prescription drugs affordable here in the United States.

We are willing to pay our fair share in terms of the research for those prescription drugs, but the time has come to say to the rest of the world, we are not going to continue to subsidize the starving Swiss.

HELPING HAITI TO MOVE PAST CURRENT POLITICAL CRISIS

The SPEAKER pro tempore (Mr. OSBORNE). Under the Speaker's announced policy of January 3, 2001, the gentleman from Michigan (Mr. CONYERS) is recognized for 60 minutes.

Mr. CONYERS. Mr. Speaker, I will insert some materials in the RECORD about the plight of the African American farmers in this country who, having won a wonderful court decision that resulted in a consent decree, are still faced with discrimination, delayed payments and all other kinds of problems which were really the basis of them bringing the suit in 1999. So I will insert in the RECORD the Federation of Southern Cooperatives' statement, the statement of our colleague the gentlewoman from North Carolina (Mrs. CLAYTON) and my own statement.

Black farmers demands:

1. To Meet with Secretary of Agriculture Ann M. Veneman before July 16, 2002 We want confirmation of her agreement to meet by 3:30 pm today, EST.

2. An immediate moratorium on all farm foreclosures by Secretary Veneman.

3. The immediate termination of all USDA officers who have been found guilty of discrimination.

4. The Federal Court halt of all proceedings in the Pigford Consent Decree until the mess can be straightened out.

5. That the USDA ceases and desists on intercepting the federal farm program payments to farmers in the *Pigford* v. *Glickman* Class Action.

6. That the USDA cease and desist on claiming tax return payments to farmers who are part of the *Pigford* v. *Glickman* Class Action.

7. That USDA tells us the loan status of Tennessee farmer James Hood, Gerald Pettaway, Coach Perkins, Barton Nelson, Ernest Camel and Robert Young.

8. The immediate firing by Judge Paul Friedman of Al Pires and Phil Frans as lead counsel in the *Pigford* v. *Glickman* Class Action.

9. Settle the Matthew Grant (deceased), Richard Grant, Dexter Davis and Howard Coates (deceased) administrative cases by August 1, 2002 in a fair and equitable manner.

FEDERATION/LAF SUPPORTS BLACK FARMER PROTEST AGAINST USDA IN TENNESSEE DEMANDS MEANINGFUL ACROSS THE BOARD RESPONSE FROM USDA AND CONGRESS

Atlanta, GA.—This week Black farmers occupied the US Department off Agriculture's Haywood County Agricultural Extension Agency in west Tennessee. They decried the fact that even in spite of the recent law suit against the USDA, grievous violations against Black farmers continue. As the primary organization working in support of Black farmers across the south for 35 years, the Federation of Southern Cooperatives/Land Assistance Fund (Federation/LAF) supports the efforts of the ''Black Farmers and Agriculturalist Association'' as it's members occupy the USDA offices.

''We support this effort because it highlights the appalling lack of justice to Black farmers over the past century and clearly demonstrates the need for immediate and corrective steps by Mr. Bush's Agriculture Secretary, Ann Veneman'' said Ralph Paige, Executive Director of the Federation/LAF.

In 1999, Black farmers settled their suit against the USDA after years of struggle to receive information, technical assistance and loans from this agency that was touted as being the lending institution of last resort. The irony is that the USDA policies invariably are in place to support huge corporate farms at the expense of family farmers everywhere, and, in particular, Black family farmers who now struggle to hold on to their dwindling land base. In fact, in 1982 the US Commission on Civil Rights reported that the primary reason Blacks have lost land is because of the USDA itself. These facts were supported by the USDA in it's Civil Rights Action Team report in the late 1990's.

When Black farmers sued the USDA, 22,692 farmers filed claims. To date more than $615 million has been dispersed to class members. Currently only 60% of those who filed claims have received payment along with injunctive relief and thousands who were denied class status are appealing to the Monitor in the case for reconsideration. An additional 68,000 farmers filed late claims. The Federation/LAF has assisted the farmers as they struggled with the severe complications and delays in the law suit settlement process. To date, thousands of farmers who have filed late claims have yet to be processed and many of the initial claimants are still suffering from bureaucratic entanglements as they await their payment or other compensation.

Perhaps one of the most disturbing aftermaths of the law suit settlement is the assumption that things would change at USDA. This was not to be. While there is a Monitor in place to assist class members should they suffer discrimination in USDA offices, the same USDA staff that over the years has wreaked havoc on Black farmers still sit in USDA offices across the South. They have not been reprimanded or made accountable in any way for their discriminatory practices. These are the same staff who farmers face daily in USDA offices as they seek services and loans.

All this is further compounded by a USDA and Congress that continue to support corporate farmers rather than family farmers